DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 14, 2015

Covidien
Jose Marquez
Regulatory Affairs Manager
15 Hampshire Street
Mansfield, MA 02048

Re: K142335
Trade/Device Name: RapidVac™ Smoke Evacuator System (Model: SE3690)
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-Handling Apparatus For A Surgical Operating Room
Regulatory Class: Class II
Product Code: FYD
Dated: December 17, 2014
Received: December 18, 2014

Dear Mr. Marquez,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142335

Device Name
RapidVac™ Smoke Evacuator System (Model: SE3690)

Indications for Use *(Describe)*
The indications for use of the RapidVac™ Smoke Evacuator System are to remove and filter smoke and aerosols from a surgical site produced during electrosurgical and laser procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date summary prepared: January 13, 2015

510(k) Submitter/Holder

Covidien
15 Hampshire Street
Mansfield, MA 02048

Contact

Jose Marquez
Regulatory Affairs Manager
Telephone: 508-452-4160
Fax: 508-452-1941
Email: jose.a.marquez@covidien.com

Name of Device

Trade Name:	RapidVac™ Smoke Evacuator System (Model: SE3690)
Common Name:	Smoke Evacuation System
Classification Name:	Air-handling apparatus for surgical operating room (21 CFR § 878.5070, Class II, FYD).

Predicate Device

The RapidVac™ Smoke Evacuator System was compared and found to be substantially equivalent to the following products of comparable type in commercial distribution:

Device Common Name: Smoke Evacuation System
Trade Name: Visiclear™ Smoke Evacuation System
Catalog Number: VV120, VV220
510(k) Number: K131402 (cleared 3/3/2014)
Manufacturer: Buffalo Filter, LLC

Device Common Name: Smoke Evacuation System
Trade Name: Optimumm™ Smoke Evacuation System
Catalog Number: Optimumm
510(k) Number: K980915 (cleared 6/29/1998)
Manufacturer: Valleylab, Inc.

Device Description

The RapidVac™ Smoke Evacuator System consists of a painted aluminum housing, a painted solid polyurethane front panel, a high suction/high flow rate variable speed centrifugal action pump, and a multi stage filter. The system can also use accessories such as sterile tubing sets in various sizes/diameters which are single-use and are used in conjunction with ultrasonic, laser or electrosurgery generators to remove and filter the smoke from the surgical field,.

The RapidVac™ Smoke Evacuator System captures particulates and adsorbs gases from surgical smoke. The smoke evacuator is specifically designed to improve visibility and reduce potential health hazards associated with surgical smoke. It can be used in both open and laparoscopic procedures with available accessories. The RapidVac Smoke Evacuator System is designed with a high suction,

high flow rate variable speed centrifugal action pump. The ultra-quiet motor is used to draw the smoke from the surgical site through the vacuum tubing and into the system where it is passed through four stages of filtration.

Intended Use

The RapidVac™ Smoke Evacuator System is to remove and filter smoke and aerosols from asurgical site produced during electrosurgical and laser procedures.

Summary comparing the technological characteristics of the subject and predicate devices

The RapidVac Smoke Evacuation System is substantially equivalent to the predicate devices with regard to smoke evacuation technologies.

Technological and Performance Characteristics

Technical Characteristics to Support Substantial Equivalence

	RapidVac™ Smoke Evacuator System (Proposed)	**Visiclear Smoke Evacuation System (Predicate)**	**Optimmum™ Smoke Evacuation System (Predicate)**
Intended Use	Smoke evacuation and filtration	same	same
Indications	The Indications for Use of the RapidVac Smoke Evacuator System is to remove and filter smoke and aerosols from a surgical site produced during electrosurgical and laser procedures.	same	The Indications for Use of the Valleylab OptiMumm™ Smoke Evacuator system are for the removal of smoke and incidental fluids produced during electrosurgery and/or laser surgery. The removal of smoke from the surgical site improves visibility and reduces potential health hazards associated with surgical smoke.
Target Population	For physicians and trained hospital staff during the use of lasers or electrosurgery	same	same
Materials of Construction	Painted Aluminum Housing, Painted solid polyurethane front panel, Four-stage filter (prefilter, ULPA grade filter, virgin activated carbon, woven fiberglass)	Powder-Coated Aluminum Housing, ABS-PC Plastic Fascia, Insulation, Four-stage filter (prefilter, ULPA grade filter, virgin activated carbon, woven fiberglass)	Aluminum housing, Plastic front panel, Three-stage filter (prefilter, ULPA grad filter, integrated charcoal component)
Energy Used	Electrical Current	same	same
Intended Marketed Accessories	Electrosurgical pencils, tubing, hoses & adapters, sterile and non-sterile	same	same
Filtration	The ULPA filter is 99.999% efficiency at .1 to .2 micron particle size	same	The ULPA filter is 99.999% efficiency at .12 micron particle size minimum
Filter Life	25 hours	35 hours	same
Electrical Safety	Tested and compliant with IEC 60601-1 and IEC 60601-1-2.	same	same
Mechanical Safety	Tested and compliant with IEC 60601-1	same	same
Chemical Safety	Neutral pH, non-patient contact	same	same
Thermal Safety	Operation of device does not result in harmful temperatures,	same	same

	tested and compliant per IEC 60601-1		
Radiation Safety	Non-radioactive	same	same

Performance

The performance verification of the RapidVac Smoke Evacuator System showed that the device met the technical and performance design requirements. Filter life verification testing was conducted for the device to confirm that the ULPA (Ultra Low Penetration Air) efficiency of the filter for the maximum flow rate (25 hours) and filter lifetime. Flow verification testing was conducted for the RapidVac device to verify flow performance outlined in the design specification. The results indicated that the product met all specified flow requirement for each mode of operation. Product verification and validation testing was conducted to confirm that the RapidVac Smoke Evacuator System meets all product requirements. Smoke removal verification testing was completed through flow verification testing. Reliability testing was conducted to demonstrate the use life of the device and show no degradation in performance over that life span. Laparoscopic Smoke Evacuation Verification was conducted for the RapidVac Smoke Evacuation System to confirm the ability to maintain pneumoperitoneum while effectively clearing smoke. Smoke Removal Effectiveness was also conducted with the subject device to demonstrate and quantify via particulate count, the ability of RapidVac to remove aerosols from electrosurgical and laser surgeries.

There was no clinical or pre-clinical performance testing needed to determine the performance of the RapidVac™ Smoke Evacuator System and to make a substantial equivalence comparison.

The RapidVac™ Smoke Evacuator System and accessories were evaluated for mechanical, electrical, performance, and sterility safety using the following standards: IEC 60601-1:2005 and IEC 60601-1-2:2007.

Conclusion

The Electrical (IEC 60601-1:2005), Mechanical, Software, and Safety (IEC 60601-1-2:2007) and performance testing of the RapidVac™ Smoke Evacuator System has shown it to be substantially equivalent to the predicate devices, Visiclear™ Smoke Evacuation System (K131402) and Optimmum™ Smoke Evacuation System (K980915).